





UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20201 www.nsptc.gov

APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.			
09/763,985 02/28/2001		02/28/2001	Kyogo Itoh	0020-4817P	3467			
2292	7590	01/07/2003						
		KOLASCH & BI	RCH .	EXAMINER				
PO BOX 747		22040-0747		HELMS, LARRY RONALD				
TALLS CIT	ikch, va	22040-0747						
				ART UNIT	PAPER NUMBER			
			1642	12				
			DATE MAILED: 01/07/2003	19				

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
	09/763,985	ITOH ET AL.	
Office Action Summary	Examiner	Art Unit	
	Larry R. Helms	1642	
The MAILING DATE of this communication app Period for Reply	pears on the cover she	et with the correspondence addres	s
A SHORTENED STATUTORY PERIOD FOR REPL THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a replent of the period for reply is specified above, the maximum statutory period Failure to reply within the set or extended period for reply will, by statute. - Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). Status	36(a). In no event, however, my within the statutory minimum will apply and will expire SIX (6), cause the application to become	ay a reply be timely filed of thirty (30) days will be considered timely. MONTHS from the mailing date of this commune ABANDONED (35 U.S.C. § 133).	nication.
1) Responsive to communication(s) filed on 19 /	<u> August 2002</u> .		
2a) This action is FINAL . 2b) ⊠ Th	is action is non-final.		
3) Since this application is in condition for allow closed in accordance with the practice under			erits is
Disposition of Claims			
4)⊠ Claim(s) <u>3-34</u> is/are pending in the application	1.		
4a) Of the above claim(s) <u>6-18 and 21-31</u> is/are	e withdrawn from cons	ideration.	
5) Claim(s) is/are allowed.			
6)⊠ Claim(s) <u>3-5,19,21 and 32-34</u> is/are rejected.			
7) Claim(s) is/are objected to.			
8) Claim(s) are subject to restriction and/o	r election requirement		
9)⊠ The specification is objected to by the Examine	r		
10) ☐ The drawing(s) filed on is/are: a) ☐ acce		by the Examiner	
Applicant may not request that any objection to th	· — •	•	
11) The proposed drawing correction filed on			
If approved, corrected drawings are required in re	ply to this Office action.		
12) ☐ The oath or declaration is objected to by the Ex	aminer.		
Priority under 35 U.S.C. §§ 119 and 120			
13) Acknowledgment is made of a claim for foreign	n priority under 35 U.S	.C. § 119(a)-(d) or (f).	
a)⊠ All b)□ Some * c)□ None of:			
 Certified copies of the priority document 	s have been received.		
2. Certified copies of the priority document	s have been received	in Application No	
3. Copies of the certified copies of the prio application from the International Bu* See the attached detailed Office action for a list	reau (PCT Rule 17.2(a)).	je
14) ☐ Acknowledgment is made of a claim for domesti	c priority under 35 U.S	S.C. § 119(e) (to a provisional app	lication).
 a) ☐ The translation of the foreign language pro 15)☐ Acknowledgment is made of a claim for domest 			
Attachment(s)			
 Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 	5) 🔲 Notic	view Summary (PTO-413) Paper No(s) e of Informal Patent Application (PTO-152 :	

Art Unit: 1642

DETAILED ACTION

Election/Restrictions

- 1. Applicant's election of Group I, claims 1-5, 19 and 7-8 and 21 in part in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
- 2. Claims 6, 9-18, 20, 22-31 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11.
- 3. Claims 1-2 have been canceled.

Claims 3-4, 7-8, 19, 21, 23, 25-26 and 32 have been amended. Claims 19 and 32 were amended in the amendment filed 10/22/02.

Claims 32-34 have been added.

4. Claims 3-5, 7-8, 19, 21, 32-34 are under examination.

Specification

5. The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, such as for example on pages 21, 29, and 66.

Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code throughout the application. See MPEP § 608.01.

Appropriate correction is required.

Page 3

Application/Control Number: 09/763,985

Art Unit: 1642

3

Claim Rejections - 35 USC § 112

- 6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- 7. Claims 3-5, 7-8, 19, 21, 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
- a. Claim 32 and those dependent from claim 32 are indefinite for reciting "wherein said polynucleotide encodes a tumor antigen protein" in claim 32 part (c) because the exact meaning of the phrase is not clear. It is not clear which polynucleotide encodes a tumor antigen is it that in part (c) or those in parts (a) or (b).
- b. Claim 19 and those that depend from claim 19 are indefinite for reciting "peptide fragments of the protein" in claim 19 because the exact meaning of the phrase is not clear. It is not clear if the peptide fragments are the entire protein encoded by the DNA encoding SEQ ID NO:2 or SEQ ID NO:1 or are only the fragments in part (c).
- c. Claim 33 is indefinite for reciting "at least one of the nucleic acids of claim 19" because claim 19 only has one nucleic acid.
- 8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the

Art Unit: 1642

art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 3-5, 7-8, 19, 21, 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to polynucleotides which hybridizes with a polynucleotide of (a) to (b) under stringent conditions wherein the polynucleotide encodes a tumor antigen protein (see claim 32). While the amino acid sequence of SEQ ID NO:2 and the polynucleotide sequence of SEQ ID NO:1 are adequately described in the specification as-filed, thereby providing an adequate basis for the polypeptide of SEQ ID NO:2 and the polynucleotide of SEQ ID NO:1; there is insufficient written description as to the identity of a polynucleotide that hybridizes to the DNA encoding SEQ ID NO:2 or SEQ ID NO:1 and encodes a tumor antigen protein. Consequently, the specification does not provide an adequate written description of a polynucleotide that hybridizes to the DNA encoding SEQ ID NO:2 or SEQ ID NO:1 and encodes a tumor antigen protein.

The specification as filed does not provide adequate written description support for a polynucleotide that hybridizes to the DNA encoding SEQ ID NO:2 or SEQ ID NO:1 and encodes a tumor antigen protein. Thus a broad genus having potentially highly diverse sequences and functions (the specification discloses a method for identifying tumor antigen peptides on page 22, lines 18-26, however, the specification discloses "if the candidate induces CTL...it is indicated that the particular candidate peptide may function as a tumor antigen peptide") is encompassed by the phrase and conception

Art Unit: 1642

cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. The specification indicates that the candidate "may" function as a tumor antigen but the specification does not set forth a definitive definition or activity or function that is readily screenable to determine a tumor antigen. Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See <u>Fiers v. Revel</u>, 25 USPQ2d 1601, 1606 (CAFC 1993) and <u>Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.</u>, 18 USPQ2d 1016.

Therefore, only a polypeptide that encodes SEQ ID NO:2 and SEQ ID NO:1 meets the written description provision of 35 U.S.C. 112, first paragraph. <u>Vas-Cath Inc. v. Mahurkar</u>, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See <u>Vas-Cath</u> at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See <u>University of California v. Eli Lilly and Co.</u> 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications
Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol.
66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

Art Unit: 1642

10. Claims 3-5, 7-8, 19, 21, 32-34 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986). They include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

The claims are broadly drawn to polynucleotides which encode SEQ ID NO:2 or polynucleotides of SEQ ID NO:1 or polynucleotides which hybridize with the polynucleotide encoding SEQ ID NO:2 or the polynucleotide of SEQ ID NO:1 and expression plasmids comprising such and transformants comprising such and pharmaceutical compositions comprising polynucleotides encoding SEQ ID NO:2 or SEQ ID NO:1 or polynucleotides which hybridize with the polynucleotide encoding SEQ ID NO:2 or the polynucleotide of SEQ ID NO:1 and pharmaceutical compositions for the treatment or prevention of tumors with compositions comprising polynucleotides encoding SEQ ID NO:2 or SEQ ID NO:1 or polynucleotides which hybridize with the polynucleotide encoding SEQ ID NO:2 or the polynucleotide of SEQ ID NO:1.

Art Unit: 1642

While the specification discloses how to make SEQ ID NO:1 and SEQ ID NO:2 the specification does not teach how to use the claimed invention. The specification contemplates the use of the polynucleotides in cancer vaccines for the treatment and prevention of tumors (see page 15-16), however the specification does not teach the intended use of the polynucleotides for treatment or prevention of tumors.

The specification provides no exemplification of or guidance on how to use the claimed vaccine formulation or antigen for activity immunotherapy in humans for prevention or treatment of tumors. The specification does not enable prevention of tumor and does not exemplify any such methods. The goal of tumor vaccination is the induction of tumor immunity to prevent tumor recurrence and to eliminate residual disease. However, Ezzell (J. NIH Res, 1995, 7:46-49) reviews the current thinking in cancer vaccines and states that tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run (see the entire document, particularly last paragraph) and further states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (p 48, para 6). In addition, Spitler (Cancer Biotherapy, 1995, 10:1-3) recognizes the lack of predictability of the nature of the art when she states that "Ask practicing oncologists what they think about cancer vaccines and you're likely to get the following response: "cancer vaccines don't work". Ask a venture capitalist or the director of product development at a large pharmaceutical company and you're likely to get the same response." (p 1, para 1).

Page 8

Furthermore, Boon (Adv Can Res, 1992, 58:177-210) teaches that for active immunization in human patients we have to stimulate immune defenses of organisms that have often carried a large tumor burden. Establishment of immune tolerance may therefore have occurred and it may prevent immunization and several lines of evidence suggest that large tumor burdens can tolerize or at least depress the capability to respond against the tumor (p. 206, para 2). There is no suggestion in the specification that the expression of these antigens from the polynucleotide has resulted in autoantibodies against the antigen thus it would be highly unpredictable that administration of the polynucleotide that encodes the antigen as a cancer vaccine, into patients would lead to an effective immune response against the tumor. In addition, Gaiger et al (Blood 96:1480-1489, 2000) teach that immunization with a tumor antigen WT1 did not show any effects on tumor growth in vivo 9see abstract).

In addition, claim 32 recites a polynucleotide that hybridizes with (a) or (b) which encodes a tumor antigen protein. The specification does not teach how to identify a tumor antigen (see above 112 first rejection) and as such one would not know how to use polynucleotides that hybridize to SEQ ID NO:1 or hybridize to polynucleotides that encode SEQ ID NO:2 for treatment or prevention of tumors. In addition, the function of binding to HLA antigen and are recognized by cytotoxic T lymphocytes are not a function that is specific to the protein (see claims 19 and 32).

Therefore, due the unpredictability of cancer vaccines in general, as evidenced by Ezzell, Spitler, Gaiger and Boon and in view of the insufficient guidance and/or working examples concerning the use the claimed polypeptides as vaccines, one skilled Art Unit: 1642

in the art would not know how to practice the broadly claimed invention without undue experimentation.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 12. Claims 7-8, 19, 21, 23, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al (DNA Res. 2:167-174, 1995).

The claims recite a polynucleotide encoding SEQ ID NO:2 or hybridizing to SEQ ID NO:2 which is a tumor antigen protein and polynucleotides which encode a tumor antigen wherein the tumor antigen protein gives rise to peptide fragments and bind to HLA antigen and are recognized by cytotoxic T lymphocytes and compositions comprising such. For this rejection the intended use of a pharmaceutical composition and pharmaceutical composition for treatments or prevention of tumor is given no patentable weight.

Nagase et al teach a protein identical to SEQ ID NO:2 and DNA encoding SEQ ID NO:2 (see Table 1 for KIAA0156 (see the attached sequence alignment on the back of this Office Action). The polynucleotide of Nagase et al would hybridize to SEQ ID NO:1 or the polynucleotide encoding SEQ ID NO:2 under the recited conditions and since the protein of Nagase et al is identical to SEQ ID NO:2 of the instant application, it

Application/Control Number: 09/763,985 Page 10

Art Unit: 1642

would be inherent that the protein of Nagase et al would give peptides that would bind to HLA antigen and be recognized by cytotoxic T lymphocytes.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1642

14. Claims 3-5, 7-8, 19, 21, and 32-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagase et al (DNA Res. 2:167-174, 1995) as applied to claims 7-8, 19, 21, 32-33 above, and further in view of Campbell (Monoclonal antibody technology, Elsevier Science Publishers, Chapter 1, pages 1-32) and Sambrook et al (Molecular Cloning, A Laboratory Manual, Chapters 3 and 12, 1989).

Claims 7-8, 19, 21, 32-33 have been described supra. Claims 3-5, and 34 recite an expression plasmid with the polynucleotide and a transformant transformed with the expression plasmid and a method of producing the protein.

Nagase et al has been described supra. Nagase et al does not teach an expression plasmid or a transformant with the expression plasmid. This deficiency is made up for in the teachings of Campbell and Sambrook et al.

Campbell teach that it is customary now for any group working on a macromolecule to both clone the genes coding for it an make monoclonal antibodies to it for basic research (see page 29).

Sambrook et al teach expression plasmids and host cells for expression of proteins.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have placed the DNA of Nagase et al in an expression plasmid to produce the protein.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have placed the DNA of Nagase et al in an expression plasmid to produce the protein because Campbell teach it is customary now

Application/Control Number: 09/763,985 Page 12

Art Unit: 1642

for any group working on a macromolecule to both clone the genes coding for it an make monoclonal antibodies to it for basic research (see page 29). In addition, one of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have placed the DNA of Nagase et al in an expression plasmid to produce the protein because Sambrook et la teach expression vectors and methods of expression of the DNA for structural and biochemical analysis (see page 16.2). Thus, It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have placed the DNA of Nagase et al in an expression plasmid to produce the protein because it is routinely done in basic research to further characterize the protein.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

- 11. No claim is allowed.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be

Art Unit: 1642

reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

J.M.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

Page 13

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ALIGNMENTS

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RESULT 1

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1 (base, 1 to 360)

Nagase, 1 to 360, N., Tanaka, A., Ishikawa, K. and Nomura, N. Prediction of the coding sequences of unidentified human genes. IV. The coding sequences of 40 new genes (KIRA0121-KIRA0160) deduced by analysis of cDNA clones from human cell line KG-1
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Submitted (11-AUG-1995) Osamu Ohara, Kazusa DNA Research Institute,
1532-3, Yana, Kisarazu, Chiba 292-0812, Japan
(E-mail:cdnainfo@kazusa.or.jp, Tel:+81-438-52-3913)
Location/Qualifiers
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3733 GAAGTGGGTGTACCTTGCTTTACCTAATAGATGTGTAAATAGAACTTTTGTAAGTC 3788
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(ra,O., Nagase,T., Kikuno,R. and Nomura,N.
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gene, complete cds.
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/organism="Homo sapiens"
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/cell_type="myeloblast"
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/gene="KIAA0156"
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3361 GGGAAGTCAGCTATAAAACATTTGCTGGAGTTTTGTTCATGGGGCTGTGCATTTTTATA 3420	132 ttatgtgtttgtaaatgacatgtcagc	3421 TTATGTGTTTGTAAATGACATGTCAGOOTTGTTTCATGTTTCCTAAAAGCAGAATATTT 3480	492 gcaacatttgttttgtataggaattatttgtgccacctgctgtggactgttttctttgcc 3551	3481 GCAACATTGTTTTGTATAGGAATTATTGTGCCACCTGCTGTGGACTGTTTTCTTTGCC 3540	3552 tagtgactagtgacctgtgttgtctaaacatgagtttcagcctttggttttgtttaata 3611	3541 TAGTGACTAGTGACCTGTGTTGTCTAAACATGAGTTTCAGCCCTTTGGTTTTGTTTAATA 3600	3612 ccatgicaaatgcaaacttcaattctccccatttagctttattaaactgacgttctctc 3671	3601 CCATGTCAAATGCAAACTTCACCCATTTAGCTTTAAATTAAACTGAGGTTTCTCTCCACCATTTAGCTTTAAATTAAAACTGAGGTTTCTTCTCTCTC			
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